

FEB 01 2002

K014016

## 510(k) SUMMARY

### 1. Submitter Information:

Name: Minntech Corporation  
Address: 14605 28<sup>th</sup> Avenue North, Minneapolis, Minnesota 55447  
Contact Person: Mark Murphy  
Date Prepared: November 1, 1999

### 2. Device Name:

Proprietary name: Minntech EnGUARD™ CHC Dual Reservoir Cardioplegia Heater/Cooler  
Common name: Heater-Cooler  
Classification name: Temperature Controller, Cardiopulmonary Bypass per 21 CFR 870.4250

### 3. Predicate Device:

Cincinnati Sub-Zero Hemotherm Model 400 Cooler/Heater

### 4. Device Description:

The Minntech EnGUARD™ CHC Dual Reservoir Cardioplegia Heater/Cooler is a portable heating and cooling circulation system with mechanical controls for delivery of warm or cool water to flow through type water pathway cardioplegia heat exchanger devices.

### 5. Intended Use:

The Minntech EnGUARD™ CHC Dual Reservoir Cardioplegia Heater/Cooler is intended to be used as a self-contained temperature control device designed to deliver cooled or heated water to a cardioplegia heat exchanger in the cardiopulmonary bypass circuit.

## 6. Technological Characteristics:

A comparative summary of the EnGUARD™ CHC Heater/Cooler and predicate device is as follows:

Characteristic	EnGUARD™ CHC Dual Reservoir Cardioplegia Heater/Cooler	Cincinnati Sub-Zero Hemotherm Model 400 Cooler/Heater
Reservoirs/construction	Dual/plastic	Dual/plastic
Power requirements	100, 115. 240 VAC	100, 115. 240 VAC
Reservoir Capacity	Cool - 8 liters	Cool - 7.6 liters
	Heat - 6 liters	Heat - 5.7 liters
Fluid Heating Range	25°C to 42°C	25°C to 42°C
Fluid Cooling Range	Ice Water temperatures	32°C to 3°C
Connections	1/2" Hansen Fittings	1/2" Hansen Fittings
Hi Limit Temperature Control	43°C	44°C

## 7. Performance Testing:

The following performance testing was conducted to determine device effectiveness as a cardioplegia heater/cooler: Heating and Cooling Systems performance, Electrical Safety Testing and Water Bath Management.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 01 2002

Ms. Lynn Lueders  
Director, Regulatory Affairs  
Minntech® Corporation  
14605 28<sup>th</sup> Ave. N.  
Minneapolis, MN 55447

Re: K014016  
Trade Name: EnGUARD™ CHC Dual reservoir Cardioplegia Heater/Cooler  
Regulation Number: 21 CFR 870.4250  
Regulation Name: Cardiopulmonary bypass temperature controller.  
Regulatory Class: Class II (two)  
Product Code: DWC  
Dated: November 27, 2001  
Received: December 5, 2001

Dear Ms. Lueders:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

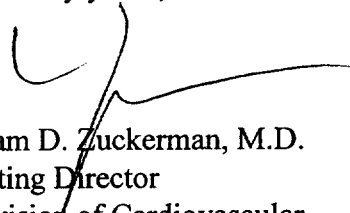
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systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.  
Acting Director  
Division of Cardiovascular  
And Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number (if Known): \_\_\_\_\_

Device Name: EnGUARD™ CHC Dual Reservoir Cardioplegia Heater/Cooler

Indications for Use:

The Minntech Corporation's EnGUARD™ CHC Dual Reservoir Cardioplegia Heater/Cooler is intended to be used as a self-contained temperature control device to deliver cooled or heated water to a cardioplegia heat exchanger in the cardiopulmonary bypass circuit.

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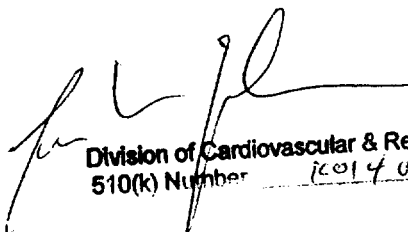
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per21 CFR 801.109)

OR

Over-the Counter-use \_\_\_\_\_  
(Optional Format 1-1-96)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K014016